DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: CPI® Ventak® P2 AICD System
Docket No. 95E-0183

#18

SEP 25 1995

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 34,879 filed by Cardiac Pacemakers, Inc., under 35 U.S.C. § 156. The medical device claimed by the patent is CPI® Ventak® P2 AICD System, Premarket Approval Application (PMA) number P930035.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act.

The PMA was approved on March 10, 1995, which makes the submission of the patent term extension application on May 8, 1995, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Peter Forrest
Cardiac Pacemakers, Inc.
Mail Stop A390
4100 Hamline Avenue North
St. Paul, MN 55112-5798